Title:
Simulation Training for Labor and Delivery Providers to Address HIV Stigma During Childbirth in Tanzania

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## PROTECTION OF HUMAN SUBJECTS

### Risks to Human Subjects

***Human subjects involvement and characteristics***

The study will be located in six health facilities in the Moshi and Rombo Districts of the Kilimanjaro Region of Tanzania. In the Moshi district we will work in: Majengo Health Center, Pasua Health Center, and St. Joseph Hospital. In the Rombo district we will work in: Tarakea Health Center, Karume Health Center and Haruma Hospital. The study includes two phases: Phase 1 to develop the intervention and Phase 2 to pilot test the intervention.

***Our report to clinicaltrials.gov reports on the Phase 2 pilot test of the intervention, which includes intervention delivery and assessment with 60 health care providers recruited from six clinic sites***.

***Recruitment of human subjects***

To recruit the health care providers, the study PI (Dr. Mmbaga) and study coordinator will conduct a brief presentation at each of the study clinics. The study coordinator will then approach providers individually to invite them to participate in the study.

***Data collection and intervention procedures***

Labor and delivery providers who are interested in enrolling in the study will be orally administered the informed consent by the study researcher. Participants will then complete structured baseline surveys. The survey will include constructs such as practices of respectful maternity care, stigma toward WLHIV, self efficacy and clinical knowledge. All enrolled providers will be invited to attend the *MAMA* intervention which will be delivered in a two-day training retreat, followed by a 1-day on-site follow-up one month later. Two months later, a post test will be administered. Participants will receive 5,000 TSh (~3 USD) for participation in the surveys and 25,000 TSh (~15 USD) per day for participating in the intervention. All intervention sessions will be video recorded for subsequent review of fidelity and thematic coding of participant input.

***Sources of materials***

Data will be obtained expressly for the proposed study by research staff and will be accessible only to the investigators and research staff. Data will be collected via structured assessments completed by the participant on paper. Some personal information, including first name, phone number and address, will be collected for following up with participants. This information will not be linked to any data, and it will be destroyed after study activities conclude. It will be securely stored away from other study data. Only the study researcher assigned to the clinic and responsible for doing follow-up will have access to participants' contact information. University of Utah staff will have no way to link data to a participant's identity.

**Data management to ensure protection of human subjects**

The MPIs, in consultation with Dr. Mmbaga and the KCMC study coordinator, will oversee the data management protocol and established SOPs for data collection, quality control, and data extraction and transfer.

Paper surveys will be reviewed for completeness by the study researcher and entered in REDCap, with paper copies stored in a locked filing cabinet at the KCRI study office. REDCap (Research Electronic Data Capture) provides a secure, HIPAA compliant, web-based interface for users to enter data and have real time validation rules (including automated data type and range checks) at the time of entry. In the case of ASASI data collection, then the data will be transferred from QDS software to our secure Box folder. Data management reports will be made to the study team weekly to ensure data integrity.

Each participant will be assigned a unique study ID number, and all data will be de-identified and coded with ID numbers only. The key linking participant names and ID numbers will be stored in a separate password protected document on a password protected computer, to which only essential study staff will have access. Locator data (including phone number, home address, and/or medical record number) will be stored as a paper file in the office, accessible only to the study researcher at the clinic who is responsible for doing study follow-up. Access to data storage areas and computers will be restricted. Transfer of data from KCMC to the University of Utah will be done via Box, which complies with the security and privacy protections for protected health information.

***Potential risks***

The well-being of study participants is of utmost importance. The study procedures that have been selected

are minimally invasive and associated with minimal risk; alternative procedures with lower risk are not available. Nevertheless, the protocol raises three general areas of human subjects concerns: confidentiality; emotional distress during the research contacts; and participant compensation. The following section describes each of these risks and the measures that will be taken to minimize them.

**Adequacy of Protection Against Risks**

***Informed consent***

Prior to participating in the study, participants will provide informed consent. A research assistant will describe the study in detail to the participant in Kiswahili, allow individuals ample time to read the consent form thoroughly (or have it read to them) and ask questions, and ensure that they understand the purpose of the study, study procedures involved, and potential risks. IDI participants will be informed that their interviews will be recorded, and will be asked to provide additional consent if they agree to audio recording. Verification of comprehension of informed consent will be accomplished by asking participants to recall central points in the consent process. This procedure will also provide an opportunity to clarify any points of confusion. Participants will sign one copy of the informed consent form and will be given a copy for their personal records. Participants will be told at enrollment that their decision to participate or not will in no way affect their current or future employment or health care at the facility.

***Protection against risks***

***Confidentiality*.** Confidentiality is of critical importance, and we will take many precautions to protect against the possibility of a breach of confidentiality. Our research team is very aware of the importance of maintaining strict confidentiality and has extensive experience dealing with sensitive information. The following precautions will protect the privacy of participants and maintain confidentiality of research data:

(1) All staff will be well trained in confidentiality and data security procedures.

(2) Privacy will be maintained by conducting all study assessments and intervention components in closed and private rooms.

(3) Each participant will be assigned a unique study ID number, and all data will be de-identified and coded with ID numbers only. The key linking participant names and ID numbers will be stored in a separate password protected document on a password protected computer, to which only essential study staff will have access.

(4) Locator data (including phone number, home address, and medical record number) will be stored as a paper file in the study office, accessible only to the study researchers who are responsible for doing follow-up and medical record abstraction.

(5) Quantitative data (participant assessments) will be entered into RedCap (Research Electronic Data Capture), a secure, web-based application designed to support data entry and transfer. RedCap is HIPAAA-compliant and secure, with data stored on Utah servers behind firewall. Paper surveys will be stored in a locked file at the KCRI study office.

(6) Analysis will occur exclusively on de-identified data.

(7) Data will only be stored for as long as necessary to complete the study, and for adherence to IRB regulations. Thus, while we acknowledge that a breach of confidentiality is possible, the likelihood is very low.

***Emotional distress*.**

The surveys will focus on provision of clinical care and their attitudes toward their patients who are living with HIV. It is possible that these conversations (especially those occurring in groups) may be distressing to health care providers who are living with HIV themselves, or who have personal experiences with HIV in their families or communities. The research staff will be careful to remind providers that they do not have to disclose personal information in groups that they do not want to be known to others.

All research staff will be extensively trained on study procedures related to emotional distress, including assessment of safety and risk, the conduct of interviews that elicit personal information, and the importance of being sensitive to and respectful of all participants. Research staff will be trained on how to identify and manage participant distress, and when to terminate an interview and/or provide referrals for a higher level of services. Research staff will be knowledgeable about relevant social and health services and will be capable of accessing appropriate resources in the area. For study participants who express severe distress, including suicidal ideation, we will have immediate access to crisis intervention through the psychiatric nursing service at Kilimanjaro Christian Medical Center.

***Participant compensation*.** We are aware of the ethical considerations in providing participant incentive payments to people living in poverty because providing cash incentives can unintentionally coerce participation in research. We will provide limited compensation for all data collection activities (equivalent to 3 USD per data collection point) and a “sitting fee” to attend the intervention (equivalent to 15 USD per day), which is consistent with standard practices for training in Tanzania.

**Potential Benefits of the Proposed Research to Human Subjects and Others**

The risk/benefit ratio for this study is relatively low, primarily because all of the data collection and intervention procedures are minimally invasive. All procedures will be performed by trained research staff to minimize risks, discomfort, and adverse events. The goal of the research is to develop an intervention with the goal of future scale-up and implementation; therefore, we expect that the results of this study will inform a training curriculum that can improve the labor and delivery experience for WLHIV.

We believe that the potential risks of this study, which are minimal and unlikely to occur, are reasonable given the potential benefits to inform future service implementation. This study poses no immediate physical risk to participants, and we have developed a thorough plan of action in the instance that adverse events occurs. Our study team has significant experience working with this population, and we are confident in both our assessment of potential risks and our ability to handle such risks. As such, we believe that the potential benefits outweigh the risks posed to human subjects.

**Importance of Knowledge to be Gained**

This research is expected to yield important new information about labor and delivery services for women living with HIV and how non-stigmatizing care can be delivered in Tanzania. The training curriculum that we develop and pilot test in Tanzania can inform future interventions in this and similar settings.